

Docket No.: 085742-0010

**PATENT**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: Patent Number: 7,514,100  
Benjamin OSHLACK

Application No.: 10/660,349

Filed: September 11, 2003

For: CONTROLLED RELEASE HYDROCODONE FORMULATIONS

**PETITION UNDER 37 CFR 1.183**

Mail Stop Petition  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

Under 37 CFR 1.183, on petition of the interested party, the Director or the Director's designee may suspend or waive, in an extraordinary situation and when justice requires, any requirement of the regulations which is not a requirement of the statutes. This Petition Under 37 CFR 1.183 requests that the Director suspend or waive any requirements of the regulations so that the Director may reset the date of the Patent Term Adjustment Determination by the U.S. Patent and Trademark Office ("PTO") to make timely a request for reconsideration of the patent term adjustment calculation for U.S. Patent No. 7,514,100, filed as Application No. 10/660,349 on September 11, 2003 and issued on April 7, 2009.

This Petition under 37 CFR 1.183 also requests the Director to take any other actions that will permit the reconsideration of the Patent Term Adjustment for this patent to accommodate recalculation under the terms of *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010).

This patent falls into a category of patents entitled to additional patent term adjustment (PTA) with no regulation to provide for the granting of such PTA. This petition is accompanied by the \$400 fee set forth in 37 CFR 1.17(f).

This Petition seeks correction of an extraordinary and unjust situation arising out the patent regulations. The '100 patent is entitled to PTA of 1,004 days under a correct interpretation of 35 U.S.C. § 154. The PTO granted only 668 days using a calculation that was only recently determined to be incorrect in *Wyeth*. The PTO decided not to appeal the *Wyeth* decision. It is extraordinary and unjust to deprive the instant patent of the valuable patent adjustment it is due under the statute.

The U.S. Patent & Trademark Office ("PTO") permits a Request for Recalculation of Patent Term Adjustment in View of Wyeth (PTO/SB/131) for patents issued before March 2, 2010, that were not issued more than 180 days before the Request was filed. The instant patent does not fall within this time period restriction.

The arbitrary date restrictions for PTA recalculation of patents falling victim to the PTO's old, pre-*Wyeth* calculation deprives patents falling outside of the date requirements for filing a Form PTO/SB/131 of a means to obtain the valuable patent term adjustment due them. PTA under 35 U.S.C. § 154 is in effect for applications filed after May 29, 2000. The instant patent was filed after this date. It is unjust, but correctable under this Petition, to deprive the patent of its due PTA under the statute, particularly since the PTO has voluntarily changed the way it makes the calculation. Any delay or need for adjustment is not the fault of the patentee.

## **Summary of Patent Term Adjustment under 35 U.S.C. § 154**

35 U.S.C. § 154 guarantees that the PTO will provide at least one notification under section 132 or a notice of allowance not later than 14 months after the date on which the application was filed, and subsequent notifications within four months of an applicant's response. PTO delays beyond these times are referred to as "A" delays.

35 U.S.C. § 154 further guarantees no more than 3-year application pendency. This does not include time consumed by continued examination requested by the applicant. PTO delays beyond this 3-year period are referred to as "B" delays. PTO delays do not include "overlap" under 35 U.S.C. § 154(b)(2)(A). Applicant delay is deducted from the PTO delay to arrive at the PTA.

### **PTO Practice Prior to *Wyeth***

Prior to the Federal Circuit's holding in *Wyeth v. Kappos*, 591 F.3d 1364 (Fed. Cir. 2010), the PTO interpreted "no overlap" under 35 U.S.C. § 154 to mean that any A delay would necessarily result in B delay. Thus, an applicant was entitled to a PTA equal to the greater of the two types of delay, but not both.

### **The Correct Calculation under *Wyeth***

In *Wyeth*, the Federal Circuit stated that: "[n]o overlap happens unless the violations occur at the same time." *Id.* at 1369-70. According to *Wyeth*, an applicant can be entitled to both A and B delays because no B delay occurs before the 3-year pendency date. Thus, there can be no overlap for A delays occurring before the 3-year pendency date.

## **The PTO's Old Calculation Deprived the Applicant of 336 Days of PTA**

The PTO calculated 668 days of PTA for the instant '100 patent. As illustrated below, the correct calculation under *Wyeth* is 1004 days. A copy of the prosecution history, downloaded from the PTO's PAIR database is attached as Exhibit A.

### **(a) A Delays**

#### **(i) Applicant filed a Response after Non-Final Action on January 14, 2005.**

The PTO mailed an *Ex Parte Quayle* Action on May 31, 2005. The PTO Action was 17 days beyond 4-months from the May 31, 2005 Response, resulting in a 17 day A delay.

**(ii) Applicant filed a Response after *Ex Parte Quayle* Action on June 27, 2005.** The PTO's next Office Action was mailed on October 4, 2007. This Action was 707 days beyond 4 months from the June 27, 2005 Response, resulting in a 707 day A delay.

### **(b) B Delay**

The '349 application was filed on September 11, 2003. A Request for Continued Examination (RCE) was filed on September 15, 2008. This resulted in a B delay of 735 days as follows. Three years from September 11, 2003 is September 11, 2006. The interval between September 11, 2006 and the September 15, 2008 RCE filing date is 735 days.

### **(c) Overlap**

The overlap is the period of A delay extending beyond the 3-year pendency date into the B delay period. Here, this is the period from September 6, 2006 to October 4, 2007 and is an overlap of 388 days.

(d) Non-overlapped PTO Delay

The non-overlap delay is  $17 + 707 + 735 - 338 = 1,071$  days.

(e) Applicant Delays

(i) Applicant delay was 61 days for the period in excess of three months for the Response filed March 5, 2008 following the October 4, 2007 Non-Final Rejection;

(ii) Applicant delayed 3 days for the period in excess of three months from the RCE filed September 15, 2008 following the June 12, 2008 Final Rejection, and

(iii) Applicant delayed 3 days for the period in excess of three months for the Issue Fee payment received February 20, 2009 following the November 17, 2008 Notice of Allowance.

(iv) The total applicant delay was  $61 + 3 + 3 = 67$  days.

**PTA under Wyeth**

The correct PTA is  $1,071 - 67 = 1,004$  days.

**Conclusion**

As detailed above, the '100 patent should have been granted 1,004 days of PTA. The PTO, using the old, incorrect calculation method, granted 668 days of PTA. Thus, the applicant was deprived of 336 days of patent term adjustment it should have been accorded under the statute. The PTO has provided a means for patents issued before March 2, 2010 to have a recalculation of their PTA via a Request for Recalculation of Patent Term Adjustment in View of

Wyeth (PTO/SB/131) as long as the patent was not issued more than 180 days before the Request was filed. No regulation provides for a recalculation of the PTA for patents falling under 35 U.S.C. § 154 but outside of the PTO's arbitrary date restrictions. This is an extraordinary and unjust result that can be remedied by a grant of this Petition to have the PTO reset the clock and recalculate the PTA in the instant case and that the PTO recognize the additional PTA due this patent.

Please charge any shortage in fees due in connection with the filing of this paper, including extension of time fees, to Deposit Account 500417 and please credit any excess fees to such deposit account.

Respectfully submitted,

McDERMOTT WILL & EMERY LLP



Paul M. Zagar  
Registration No. 52,392

**Please recognize our Customer No. 20277  
as our correspondence address.**

600 13<sup>th</sup> Street, N.W.  
Washington, DC 20005-3096  
Phone: 212.547.5400 PMZ:MWE  
Facsimile: 202.756.8087  
**Date: July 21, 2010**

# **EXHIBIT A**

## **Transaction History**



**Patent eBusiness**

- [Electronic Filing](#)
- [Patent Application Information \(PAIR\)](#)
- [Patent Ownership](#)
- [Fees](#)
- [Supplemental Resources & Support](#)

**Patent Information**

- [Patent Guidance and General Info](#)
- [Codes, Rules & Manuals](#)
- [Employee & Office Directories](#)
- [Resources & Public Notices](#)

**Patent Searches**

- [Patent Official Gazette](#)
- [Search Patents & Applications](#)
- [Search Biological Sequences](#)
- [Copies, Products & Services](#)

**Other**

- [Copyrights](#)
- [Trademarks](#)
- [Policy & Law Reports](#)

**Secured Patent Application Information Retrieval**

[XML Download](#)    [Order Certified Application As Filed](#)  [Order Certified File Wrapper](#)  [View Order List](#)

**10/660,349** **CONTROLLED RELEASE HYDROCODONE FORMULATIONS**

Select New Case	Application Data	Transaction History	Image File Wrapper	Patent Term Adjustments	Continuity Data	Fees	Published Documents	Address & Attorney/Agent	Display References
<b>Transaction History</b>									
Date	Transaction Description								
04-07-2009	Recordation of Patent Grant Mailed								
03-18-2009	Issue Notification Mailed								
04-07-2009	Patent Issue Date Used in PTA Calculation								
02-26-2009	Dispatch to FDC								
02-25-2009	Application Is Considered Ready for Issue								
02-20-2009	Issue Fee Payment Verified								
02-20-2009	Issue Fee Payment Received								
11-17-2008	Mail Examiner's Amendment								
11-17-2008	Mail Notice of Allowance								
11-14-2008	Document Verification								
11-14-2008	Notice of Allowance Data Verification Completed								
11-10-2008	Examiner's Amendment Communication								
09-22-2008	Information Disclosure Statement considered								
09-22-2008	Reference capture on IDS								
09-22-2008	Information Disclosure Statement (IDS) Filed								
10-22-2008	Date Forwarded to Examiner								
10-22-2008	Date Forwarded to Examiner								
09-15-2008	Request for Continued Examination (RCE)								
10-22-2008	Disposal for a RCE / CPA / R129								
10-04-2008	Case Docketed to Examiner in GAU								
09-22-2008	Information Disclosure Statement (IDS) Filed								
09-15-2008	Workflow - Request for RCE - Begin								
06-12-2008	Mail Final Rejection (PTOL - 326)								
06-09-2008	Final Rejection								
11-13-2007	Information Disclosure Statement considered								
04-05-2008	Date Forwarded to Examiner								
03-05-2008	Response after Non-Final Action								
03-05-2008	Request for Extension of Time - Granted								
01-08-2008	Case Docketed to Examiner in GAU								
11-13-2007	Reference capture on IDS								
11-13-2007	Information Disclosure Statement (IDS) Filed								
11-13-2007	Information Disclosure Statement (IDS) Filed								
10-04-2007	Mail Non-Final Rejection								
10-01-2007	Non-Final Rejection								
01-14-2005	Information Disclosure Statement considered								
09-11-2003	Information Disclosure Statement considered								
04-19-2007	Case Docketed to Examiner in GAU								
06-27-2005	Oath or Declaration Filed (Including Supplemental)								
04-17-2007	Date Forwarded to Examiner								
06-27-2005	Response after Ex Parte Quayle Action								
05-02-2006	Case Docketed to Examiner in GAU								
08-28-2005	Case Docketed to Examiner in GAU								
05-31-2005	Mail Ex Parte Quayle Action (PTOL - 326)								
05-26-2005	Ex Parte Quayle Action								
05-18-2005	Case Docketed to Examiner in GAU								
05-17-2005	Paralegal TD Not accepted								
09-11-2003	Preliminary Amendment								
04-05-2005	Case Docketed to Examiner in GAU								
01-14-2005	Information Disclosure Statement (IDS) Filed								
01-14-2005	Information Disclosure Statement (IDS) Filed								

02-11-2005	Date Forwarded to Examiner
01-14-2005	Response after Non-Final Action
01-14-2005	Workflow incoming amendment IFW
10-15-2004	Mail Non-Final Rejection
10-01-2004	Non-Final Rejection
07-08-2004	Case Docketed to Examiner in GAU
07-08-2004	IFW TSS Processing by Tech Center Complete
09-11-2003	Affidavit(s) (Rule 131 or 132) or Exhibit(s) Received
09-11-2003	Reference capture on IDS
09-11-2003	Information Disclosure Statement (IDS) Filed
09-11-2003	Information Disclosure Statement (IDS) Filed
12-05-2003	Application Is Now Complete
12-04-2003	Application Return from OIPE
12-05-2003	Application Is Now Complete
12-04-2003	Application Return TO OIPE
12-04-2003	Application Dispatched from OIPE
12-04-2003	Application Is Now Complete
11-24-2003	Cleared by OIPE CSR
10-20-2003	IFW Scan & PACR Auto Security Review
09-11-2003	Initial Exam Team nn

*If you need help:*

- Call the Patent Electronic Business Center at (866) 217-9197 (toll free) or e-mail [EBC@uspto.gov](mailto:EBC@uspto.gov) for specific questions about Patent Application Information Retrieval (PAIR).
- Send general questions about USPTO programs to the [USPTO Contact Center \(UCC\)](#).
- If you experience technical difficulties or problems with this application, please report them via e-mail to [Electronic Business Support](#) or call 1 800-786-9199.

You can suggest USPTO webpages or material you would like featured on this section by E-mail to the [webmaster@uspto.gov](mailto:webmaster@uspto.gov). While we cannot promise to accommodate all requests, your suggestions will be considered and may lead to other improvements on the website.